



PATENT/Docket No.: 6231.NCN1

Serial No.: 09/500,246

Page No. 1

CERTIFICATE OF MAILING (37 CFR 1.8)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1616
Examiner : F. Choi
Applicant(s) : Todd P. Foster, William M. Moseley, Satish K. Singh
Serial No. : 09/500246
Filed : 2/8/00
For : PHARMACEUTICAL IMPLANT CONTAINING IMMEDIATE
RELEASE AND SUSTAINED RELEASE COMPONENTS AND
METHOD OF ADMINISTRATION

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Washington, DC 20231

**INFORMATION DISCLOSURE STATEMENT TRANSMITTAL
UNDER 37 CFR 1.97 AND 1.98**

Sir:

Information Disclosed. The information disclosed consists of the following:

[X] **Form PL-1449.** Provided herewith are copies of patent(s) and/or publication(s) as listed in the attached form PL-1449.

[X] At least to the extent required under §1.98(a)(3), a concise explanation of the relevance of references listed in form PL-1449 is:

- [] contained in the above-captioned specification as filed;
- [X] provided in a communication enclosed with this paper;
- [] provided in the International Search Report enclosed with this paper; and/or
- [] not necessary as all of the references cited are in the English language.



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COMMUNICATION REGARDING SUPPLEMENTAL INFORMATION DISCLOSURE

Sir:

In U.S. Patent 4,576,604 the Examiner's attention is called to the statement appearing at the bottom of Column 4 continuing to Column 5 "The delivery of drug **15**, usually over a period of an hour or more, is effected independent of delivery of drug **16** by device **10**. Device **10** may deliver drug **16** during the period of time drug **15** is delivered, or device **10** may deliver drug **16** after delivering of drug **15**. Drug **15** and drug **16** may in an optional embodiment be the same drug or different drug."

In U.S. Patent 5,288,496 Applicant wishes to call Examiner's attention to statement in Column 6, line 42. "The microparticles can be mixed by size or by type so as to provide for a delivery of growth promoters to animals in a multiphasic manner and/or in a manner which provides different growth promoters to the animal at different times, or a mixture of growth promoters to the animal at the same time. Other biologically active agents commonly administered to animals may be blended with the growth promoter formulation. For example, antibiotics, anthelmintics, vaccines, or any desired active agent, either in microparticle form or in conventional, unencapsulated form may be blended with the growth promoter and provided to an animal by the method of the invention." The Examiner's attention is also drawn to Examples 10 and 11.

- ☐ ***Disclosure from Predecessor Application.*** Provided herewith is a copy (or the copy is already present in the present file wrapper in accordance with §1.53(d)) of one or more forms PL-1449 and/or search/examination reports of record in this or a predecessor application, Serial No. , filed the benefit of which is claimed under 35 USC 120. Copies of references are present in the prosecution history of the referenced application and are not supplied herewith pursuant to §1.98(d).

Basis for Consideration. This information disclosure statement is entitled to consideration by the Office under:

- ☐ **§1.97(b)**, as being filed within three months of the filing date of the above-captioned application and/or the date of entry of the National Stage, if later, and/or before the mailing date of the first Office action on the merits. Applicant(s) is/are unaware that any office action has issued in this case. However, in the event a first office action has issued, prior to the mailing of this document, then authorization is given to charge the late fee to the deposit account identified below.
- ☐ **§1.97(c)**, as being filed after the period specified in §1.97(b), but before the mailing date of a final action under §1.113 and/or the notice of allowance under §1.311. Consideration of this information disclosure statement at this time is requested for the reason checked below:
- ☐ **Authorization is hereby provided to charge Deposit Account No. 21-0718 the fee set forth in §1.17(p), \$240.00**, or such greater or lesser amount as the Commissioner may from time to time prescribe by rule. Triplicate copies of this paper are provided to facilitate the charge to the Deposit Account.
- ☐ A statement as specified in 37 CFR 1.97(e) below.
- ☐ **§1.97(d)**, as being filed after the period specified in §1.97(c), but on or before payment of the issue fee and is accompanied by:
- ☐ **Authorization to charge Deposit Account No. 21-0718 the fee set forth in §1.17(i), \$130.00**, or such greater or lesser amount as the Commissioner may from time to time prescribe by rule. Triplicate copies of this paper are provided to facilitate the charge to the Deposit Account.
- ☐ A petition requesting consideration of the information disclosure statement; and
- ☐ A statement as specified in 37 CFR 1.97 (e) below.
- ☒ **§1.97(e)**, this is a **supplemental information disclosure statement**. A prior information disclosure statement has already been filed. Applicant certifies, as provided in 37 CFR 1.97 (e), that

In U.S. Patent 5,654,008 Applicant wishes to call Examiner's attention to the statement in Column 17, beginning at line 47. "The microparticles can be mixed by size or by type so as to provide for the delivery of active agent to the patient in a multiphasic manner and/or in a manner that provides different active agents to the patient at different times, or a mixture of active agents at the same time. For example, secondary antibiotics, vaccines, or any desired active agent, either in microparticle form or in conventional, unencapsulated form can be blended with a primary active agent and provided to the patient....."

In U.S. Patent 5,792,477 Applicant wishes to call the Examiner's attention to the statement in column 17, beginning at line 55. "The microparticles can be mixed by size or by type so as to provide for the delivery of active agent to the patient in a multiphasic manner and/or in a manner that provides different active agents to the patient at different times, or a mixture of active agents at the same time. For example, secondary antibiotics, vaccines, or any desired active agent, either in microparticle form or in conventional, unencapsulated form can be blended with a primary active agent and provided to the patient."

Respectfully submitted,

John H. Engelmann
John H. Engelmann, Attorney
Registration No. 28,075

Date: MARCH 26, 2002

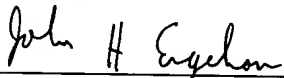
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- ☐ Each new item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this statement.
- ☒ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing below, after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this statement.

Disclaimer. In accordance with §1.97(g) and (h), the filing of this information disclosure statement is not to be construed as an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56, and is not to be construed as a representation that a search has been made.

Respectfully submitted,



John H. Engelmann, Attorney
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Date: MARCH 26, 2002

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Attachment(s)

- ☒ Form 1449 with copies of reference(s)
☐ Form 1449 from predecessor application (no references)
☒ Communication providing concise explanation of relevance
☐ International Search Report